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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,339	01/26/2004	Shawn R. Feaster	034047.003DIV1 (W 00-23B)	7108
53502 7590 05/07/2010 OFFICE OF THE STAFF JUDGE ADVOCATE (SKS) U.S. ARMY MED. RESEARCH & MATERIEL COMMAND 504 SCOTT STREET ATTN: MCMR-ZA-J (MS. ELIZABETH ARWINE) FORT DETRICK, MD 21702-5012			EXAMINER SHEN, BIN	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 05/07/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/763,339	Applicant(s) FEASTER ET AL.	
	Examiner BIN SHEN	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-36, 39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) 31-34 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29, 30, 35, 39, 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 29-36, 39, 40 are currently pending. Claims 31-34, 36 are withdrawn from further consideration.

Claims 29, 30, 35, 39, 40 are presented for examination on the merits.

Maintenance of Rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29, 30, 35, 39 are again rejected under 35 U.S.C. 102(b) as being anticipated by London (1995).

London teaches a field kit for estimation of cholinesterase in whole blood (page 59, left column, 2nd full paragraph).

Therefore, London teaches a device for detecting, measuring or monitoring cholinesterase in blood sample comprising a cartridge (read as kit) with plurality of substrates (page 59, left column, 2nd full paragraph, lines 1-3; a detector for detecting reaction rates (colorimeter, page 59, left column, 2nd full paragraph, line 5); software for calculating protein concentration (page 59, left column, 2nd full paragraph, line 5, **Claim 29**); the cartridge/kit comprises reagent, buffer standard for measuring the reaction rates (see substrate for the enzymes on page 59, left column, 2nd full paragraph, lines 1-3, since the field kit estimate cholinesterase therefore inherently contains all necessary reagent/buffer/standard for measuring the reaction rates, **Claim 30**); wherein the kit is capable of detecting cholinesterase including plasma cholinesterase and erythrocyte cholinesterase (plurality of proteins, page 59, left column, 2nd full paragraph, lines 1-2, **Claim 35**); the field kit (Test-Mate OP kit, page 57, right column, 3rd full paragraph, lines 8-9) is inherently hand-held for easy application (**Claim 39**).

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Applicant's arguments filed 3/29/2010 have been fully considered but they are not persuasive.

Applicant argues that the software according to London is not the same as the software according to the instant invention.

It is the examiner's position that the instant application claims a device and software (including the equations/formula for calculation) is not considered a structural component of the device therefore does not add patentable weight to the device, thus the art rejection still applies.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29, 40 are again rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of London and Jacobs (1993).

London's teachings anticipate claims 29 as above.

London does not teach cartridge triggers device automation when inserted.

Jacobs teaches a blood analyzer with an insertable cartridge (page 1891, left column, 1st full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify/automate the device of London by using an insertable cartridge to trigger the automation of the device (**Claim 40**) because Jacobs teaches a cartridge that can be inserted in the device. One would have been motivated to automate the device because Jacobs et al. specifically described a cartridge in a blood analyzer and one of ordinary skill in the art has good

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reason to automate the device by trigger the automation by inserting the cartridge for anticipated success in view of Jacob's teaching of an insertable cartridge for a blood analyzer.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments filed 3/29/2010 have been fully considered but they are not persuasive.

Applicant argues that neither London nor Jacobs teach/suggest the same software of instant invention to calculate the activity or the concentration of the protein using a set of equations as required by claim 29.

It is the examiner's position that the instant application claims a device and software is not considered a structural component of the device therefore does not add patentable weight to the device, thus the combination of London and Jacobs renders claims 29 and 40 obvious.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571) 272-0925.

B Shen

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/Karen Cochrane Carlson/

Primary Examiner, Art Unit 1656